Rapid HIV Tests: Issues Regarding HIV Counseling
Current Recommendations and Issues for Discussion
Rapid HIV Testing Consultation
September 10-11, 2002
Atlanta, Georgia

1. Why Provide Rapid HIV Testing?

Approximately 2.1 million HIV tests are conducted annually in publicly funded counseling, testing, and referral (CTR) programs. However, many persons do not return for their test results: 30% of persons who tested HIV-positive during 2000 and 39% of persons who tested HIV-negative did not return (HIV CT Client Record Report, 2000 U.S. Total; CDC, unpublished data). Almost all clients receive their test results with rapid tests because results can be provided at the testing visit.

2. How Do Rapid HIV Tests Compare with Standard HIV Screening Tests, Enzyme Immunoassays (EIAs)?

Clinical studies have demonstrated that the sensitivity[1] and the specificity[2] of rapid HIV tests are comparable to those of EIAs currently used for screening. The negative predictive value[3] of a screening test is high at the HIV prevalence observed in most U.S. testing settings (CDC, 1998). Therefore, a client with a negative rapid HIV test result can generally be told he or she is not infected. However, because HIV antibodies take time to develop, persons with a recent possible exposure (sexual contact or needle sharing within 3 months) might need retesting. As with any screening test, the positive predictive value of a reactive rapid HIV test is low in populations with low prevalence (see Appendix). Because some reactive test results may be false-positive, every reactive rapid test must be confirmed by a supplemental test (either Western blot or an immunofluorescence assay [IFA]), as is done currently for reactive EIA results (CDC, 1989).

3. HIV Counseling with Rapid HIV Tests

HIV counseling encompasses two components: provision of information and prevention counseling (CDC, 2001a). All clients must receive information about the rapid test and give informed consent, as is true with standard HIV testing. Clients who can benefit from prevention counseling should receive prevention counseling.

---

[1] Sensitivity is the probability that the test result will be reactive if the specimen is a true positive.
[2] Specificity is the probability that the test result will be negative if the specimen is a true negative.
[3] The predictive value of a screening test is the probability that the test result predicts the true infection status of the person tested.

A. Information

Information can be provided either in a face-to-face meeting with a counselor or in a pamphlet, brochure, or video. Clients tested with a rapid HIV test should be given the same types of information recommended for those tested with a standard EIA:

- Information about the HIV test and its benefits and consequences.
- Risks for transmission and how HIV can be prevented.
- The meaning of the test results in explicit, understandable language.
- Where to obtain further information and, if applicable, HIV prevention counseling.
- Where to obtain other services.

In addition, clients should be

- Advised that their rapid HIV test results will be available during the same visit.
- Informed of the need for confirmatory testing if the rapid test result is reactive.

Communicating the Meaning of the Rapid HIV Test Results

Negative Rapid HIV Test Results

During the initial visit, the provider can definitively tell clients who have had a rapid HIV test with a negative result that they are not infected, except for those who have had a recent (within 3 months) known or possible exposure to HIV. Retesting should be recommended for clients with a recent exposure.

Reactive (Preliminary Positive) Rapid HIV Test Results

Further testing is always required to confirm a reactive screening test result. Providing reactive (preliminary positive) results to clients without the benefit of a same-day confirmatory test has been a challenge. For all clients with a reactive rapid HIV test result, however, it is essential to:

- Explain the meaning of the reactive screening test result in simple terms, avoiding technical jargon.
- Emphasize the importance of confirmatory testing and schedule a return visit for confirmatory test results.
- Underscore the importance of taking precautions to prevent transmitting infection to others while awaiting results of confirmatory testing.

A simple message to convey this information is “Your preliminary test result was positive, but we won’t know for sure if you are HIV-infected until we get the results from your confirmatory test. In the meantime, you should take precautions to avoid transmitting the virus”.

For Discussion:
As with any screening test, explaining a preliminary positive test result involves a discussion that must be tailored to the client's needs and expectations. It is difficult to formulate a precise recommendation regarding what kind of message to give a client with reactive test results based on the probability of infection. For example, some providers may know the prevalence in the population in their setting. Many providers do not. Some clients may not reveal behaviors that increase their risk for HIV. Or a client who has risk behaviors may not be prepared to hear that he is infected. Perhaps the best approach is to be sure that the client understands the simple message and returns for his confirmatory test result.

B. HIV Prevention Counseling

HIV prevention counseling with a rapid HIV test, completed in a single visit, has been successfully implemented in several settings in the United States with the currently available SUDS test. Experience has shown that this form of prevention counseling is feasible and is well accepted by most clients as well as counselors. Essential elements of HIV prevention counseling with rapid HIV tests include:

- Keep the session focused on HIV risk reduction.
- Include an in-depth, personalized risk assessment.
- Acknowledge and provide support for positive steps already made.
- Clarify critical rather than general misconceptions about HIV risk.
- Negotiate a concrete, achievable behavior-change step that will reduce HIV risk.
- Seek flexibility in the prevention counseling approach and counseling process, avoiding a "one-size-fits-all" approach.
- Provide skill-building opportunities.
- Use explicit language when providing test results.

The main difference between prevention counseling with rapid tests and prevention counseling with standard EIA tests is that clients may have only one opportunity to meet with a counselor and to develop a risk-reduction plan. This means that clients with HIV-negative screening results do not have an opportunity to try out their risk-reduction plan prior to receiving their HIV result, and may not have an opportunity to discuss attempts at carrying out their risk-reduction plan with a counselor. An example of a counseling protocol for providing prevention counseling during one visit to clients receiving rapid test results can be found at *http://www.cdc.gov/hiv/projects/respect-2/docs/RESPECT2 RapidTestCounselingProtocol.pdf.*

4. Future of Rapid HIV Testing

Several rapid HIV tests currently being used outside the United States will likely be seeking FDA approval. Many of these tests require a single step and can be performed on whole blood, serum, plasma, oral fluid, or blood samples obtained by finger-stick. The sensitivity and the specificity of these tests are similar to those of the standard EIA (Branson, 2000). When these tests become available, it may be possible to implement strategies such as one recommended by the World Health Organization (WHO, 1997), whereby specific combinations of different rapid tests might be used to confirm reactive HIV test results on the day a person is tested.

For Discussion: Prevention counseling with rapid testing

Because rapid tests allow clients to receive results the same day, unlike the 1-2 week wait for the standard EIA, rapid HIV testing can change how and when HIV prevention counseling is delivered. Rapid HIV testing provides a result in less than half an hour. It is now possible for clients to have an HIV test, be given the result, and complete prevention counseling all in one clinic visit.

There are several options for delivering prevention counseling with rapid testing. Three examples include:

1. One-session prevention counseling. The specimen is obtained early in the visit as part of routine or regular services. The client receives HIV prevention counseling at the same time he or she is given the test result.
2. Two-session prevention counseling. The client receives one session of HIV prevention counseling before the specimen is obtained for the test and a second session when the test result is provided.
3. Two session prevention counseling. The client receives one session of HIV prevention counseling on the day he or she receives the rapid test, and returns for a second session of prevention counseling in 1 to 2 weeks.

Two brief sessions of HIV prevention counseling have been shown to be effective in reducing risk behaviors (and subsequent STDs) in high-risk clients. The effectiveness of prevention counseling completed in a single visit, compared with prevention counseling offered at two visits 1 to 2 weeks apart, is still under investigation. Therefore, it may be appropriate to suggest (or schedule) a return visit for a second session of prevention counseling for high-risk clients, and to offer that opportunity to all clients.

For Discussion: The Optimal Combination of Rapid HIV Testing and HIV Prevention Counseling in different settings.

Rapid tests make it more convenient to offer HIV testing in a variety of settings in which it may be difficult to offer standard testing. For example, CDC has recommended since 1993 that HIV testing be offered to all inpatients and outpatients ages 15-54 years in acute care hospitals with HIV prevalence of 1% or greater (CDC, 1993). Rapid HIV tests make it easier to carry out this recommendation. CDC also recommends that all pregnant women in the United States be tested for HIV infection (CDC, 2001b). Surveys have shown that some providers perceive that the difficulties and complexity of required counseling discourage them from offering HIV testing (Institute of Medicine, 1999). CDC guidelines for HIV screening recommend a simplification of the testing process so that pretest counseling is not a barrier to testing, and acknowledge that flexibility in the consent process is necessary to allow for various types of informed consent (CDC, 2001b). Determining whether and how to offer rapid HIV testing, HIV prevention counseling, or both must take into account the client base, setting, HIV prevalence level, and available resources.

References

Branson, BM. Rapid Tests for HIV Antibody. AIDS Reviews 2000; 2: 76-83.

Centers for Disease Control and Prevention *(a)*. Revised guidelines for HIV counseling, testing, and referral Revised Recommendations for HIV Screening of Pregnant Women. MMWR 2001; 50(No. RR-19):1-57.

Centers for Centers for Disease Control and Prevention *(b)*. Revised guidelines for HIV counseling, testing, and referral Revised Recommendations for HIV Screening of Pregnant Women. MMWR 2001; 50(No. RR-19):59-85.

Disease Control and Prevention. Update: HIV Counseling and Testing Using Rapid Tests – United States 1995; MMWR 1998; 47(11): 211-215.

Centers for Disease Control and Prevention. Recommendations for HIV Testing Services for Inpatients and Outpatients in Acute Care Hospital Settings. MMWR 1993; 42 (No. RR-2): 1-5.

Centers for Disease Control. Interpretation and use of the Western blot assay for serodiagnosis of human immunodeficiency virus type 1 infections. MMWR 1989; 38(suppl 7): S4-S6.

Institute of Medicine. National Research Council. Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States. Washington, DC: National Academy Press, 1999.

World Health Organization. Revised Recommendations for the Selection and Use of HIV Antibody Tests. Weekly Epidemiologic Record 1997: 72(12): 81-88.

Appendix: Positive Predictive Value of Rapid HIV Tests

Positive predictive value is an important concept that may be difficult to understand. It depends both on the test that is used (in particular, the test's specificity) and the prevalence in the population tested. An example may help to illustrate how the positive predictive value (and the proportion of false-positive test results) changes at different levels of prevalence.

We will use a test that has a sensitivity of 99.9% and a specificity of 99.8%, similar to that of current rapid HIV tests and EIAs. A specificity of 99.8% means that 0.2% (2 tests out of 1,000) will be false-positive. For this example, we will test 1,000 persons, first in an STD clinic with high HIV prevalence: 5%. Testing 1,000 persons , we would discover 50 persons who were truly positive; because of the specificity, we would also encounter 2 false-negative test results. Thus, the predictive value of a reactive test in this setting would be (50 true positive tests divided by 52 total positive tests) or 96%.

Using this same test in a population with low prevalence gives us a very different result. For this example, we will use the same test in a family planning, where the HIV prevalence is 0.1%. Testing 1,000 persons in this clinic, 1 person would be truly positive, and 2 test results would be false positive. The predictive value of the same test in this setting, therefore, would be (1 true positive test divided by 3 total positive tests) or 33%. Notice that in both these examples, the ***number*** of false-positive tests was the same, but the ***proportion*** of false-positive tests was very different.

The following table shows the positive predictive values.

Positive Predictive Value of HIV Tests in Populations with Differing HIV Prevalence[*] Example: Testing 1,000 Persons

HIV Prevalence	True Positive	False Positive	Predictive Value
10%	100	2	98%
5%	50	2	96%
2%	20	2	91%
1%	10	2	83%
0.5%	5	2	71%
0.2%	2	2	50%
0.1%	1	2	33%

[*] Calculated for test with sensitivity 99.9%, specificity 99.8%